

Medication Therapy Management Program

*Excerpted from the Medicare Prescription Drug Benefit Final Rule
42 CFR Parts 400, 403, 411, 417, and 423*

Excerpted below from the final rule governing the Medicare Prescription Drug Benefit is CMS' response to questions about the Medication Therapy Management Program (emphasis added). For more information, visit the [CMS Pharmacy MMA Website](#).

Response: After reviewing extensive comments and conducting additional research, we believe that insufficient standards and performance measures exist to support further specification for MTMP services and service level requirements, and therefore we are adopting the flexibility proposed in the proposed rule. Although best practice examples identified some common elements, neither the Booz-Allen-Hamilton report, nor any comments submitted to us, showed that these MTMPs reflected widely accepted standards of practice. In fact, until the Pharmacist Provider Coalition's recent publication of their definition of MTMP, no widely agreed upon definition of MTMP existed, let alone standards and measures. While we understand the concern with potential disincentives for part D plans to develop robust MTMPs, we are not adopting additional regulatory requirements at this time because it is unclear which specific, additional requirements would enhance MTMPs, and ultimately improve therapeutic outcomes for part D beneficiaries.

We continue to believe that MTMPs can and must offer appropriate services for targeted beneficiaries. However, we are concerned that further premature regulatory requirements at this time might not only fail to improve MTMPs, but could negatively impact their development. Requiring a universal set of minimum services and service levels, without fully understanding how they could effectively be implemented on a much larger platform than illustrated in best practice examples, could result in MTMPs becoming perfunctory services offered just to satisfy regulatory requirements as opposed to patient focused services aimed at improving therapeutic outcomes. For example, several of the best practice examples stressed the importance of collaboration with prescribers to ensure that MTMP is successful. However, simply requiring specific services and service delivery mechanisms will not do anything to ensure successful collaboration. Therefore, we believe that at the outset of the Medicare Prescription Drug Benefit, plans must have maximum flexibility to develop MTMPs that can achieve the statutory goal of improving therapeutic outcomes.

Notwithstanding the lack of current MTMP standards and performance measures, we believe that MTMP must evolve and become a cornerstone of the Medicare Prescription Drug Benefit. With an understanding that the introduction of MTMP requirements can significantly impact the current practice of pharmacy, **we intend to utilize the Medicare Prescription Drug Benefit as a platform for driving the quality improvement of prescription drug therapy. We require plans to report details on their respective MTMPs, and we intend to collaborate further with**

industry to develop measures that can be used to evaluate programs and establish appropriate standards. Our goal is to evaluate MTMPs within the context of an overall strategy that evaluates not only MTMP, but also other quality of care programs, standards, and services, such as drug utilization management, drug utilization review, chronic care improvement programs, and the role of QIOs. In so doing, we believe that we will identify best practices that will evolve into industry practice standards and could eventually be adopted as our standards.

Comment: Several commenters recommended that we require plans to allow beneficiaries to receive MTMP services from their network/non-network provider of choice. In addition, several commenters recommend that we require plans to offer MTMPs that favor face-to-face consultations over other forms of intervention.

Response: Consistent with our overall approach to MTMPs, at this time we believe plans need the discretion to decide on which methods and which providers are best for providing MTMP services available under their specific MTMP. We assume that such providers will include some network pharmacy providers, but plans are not obligated to use any specific providers as long as those providing services for the plan are qualified to provide such services. **Furthermore, although we indicated in the proposed rule that we believe pharmacists will be the primary providers of these services, and that we believe beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the appropriate providers, we recognize that such determinations must be made in the context of the specific, overall program design.** Moreover, while we understand that face-to-face consultations can offer advantages over other methods of service delivery, it is still but one component of a successful MTMP. Successful MTMPs will need to consider and coordinate not only the method of communication and the providers of services, but also other components such as the content of the service, the qualifications of the providers, the identification of targeted beneficiaries, and the documentation requirements associated with services performed. Because plans are responsible for designing the programs to improve therapeutic outcomes, plans will be in position to make the determinations that will maximize overall MTMP effectiveness, taking into account all factors that influence successful MTMP.

In addition, while section 1860D-4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered part D drugs, we do not believe the same authority applies to out of network access for MTMP services. Unlike situations when patients face an urgent need for covered Part D drugs but do not have access to a network provider, we do not believe this urgent need rationale reasonably applies to MTMP. In addition, the Congress clearly knows how to require out-of-network access and did so specifically for Part D drugs in emergency situations. Accordingly, we can not require plans to offer MTMP services through out-of-network pharmacies.